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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,254	10/02/2000	Marc F. Charette	CIBT-P01-558	9598

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/508,254

Applicant(s)

CHARETTE ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 1/15/04. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,11,13,15-23,28 and 30-32.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 1, 11, 13, 15-23 under 35 U.S.C. 103(a) as being unpatentable over Lein et al. (Int. J. Devl. Neuroscience, 1996, IDS submitted by Applicant, reference #AT) in view of Trupp et al. (J. Cell Biology, 1995) as set forth at pages 7-9 of the previous Office Action (11 July 2003) is withdrawn in view of the amendment (14 January 2004).

Continuation of 5. does not place the application in condition for allowance because claims 28, 30-32 stand rejected under 35 USC 112, first paragraph, enablement. The basis for this rejection was set forth at pages 7-9 of Office Action (27 October 2001, Paper No. 8) and maintained in Office Action (12 November 2002, Paper No. 15).


Applicants submit that using cultured neural cells in vitro to determine survival of mammalian neural cells is a proper model that reasonably correlates with the effect of the in vivo administration of morphogens and neurotrophic factors. Applicants maintain that the fact that in vitro cultures do not offer unequivocal prediction for responses of adult neurons does not indicate that the model does not provide the required correlation to support a claim for an in vivo method. Applicants submit Exhibit 1, Granholm et al. and Exhibit 2, Manabe et al.

Applicants' arguments have been fully considered but are not deemed persuasive. Granholm et al. (Exhibit 1) teach that OP-1 stimulated overall growth of spinal cord tissue. Manabe et al. (Exhibit 2) teach that GDNF decreased motor neuron loss. The instant claims are drawn to pharmaceutical preparation for promoting the survival of mammalian neural cells. The instant claims encompass a genus (neural cells). The references teach an effect with a species (motor neurons). The cited references are not applicable to the survival of all neural cells. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claims 1, 11, 13, 15-23 stand rejected under 35 USC 112, first paragraph, scope of enablement. The basis for this rejection was set forth at pages 5-7 of Office Action (12 November 2002, Paper No. 15).

Applicants maintain that the instant application teaches that morphogen combined with neurotrophic factor enhances the survival of peripheral neuron cells (PNS neurons). Applicants submit that there is no intrinsic difference between PNS neurons and CNS neurons. Applicants submit Reiriz et al. (Exhibit 3) to demonstrate that BMP-2 and a neurotrophic factor enhances the survival of CNS neurons in vitro.

Applicants' arguments have been fully considered but are not deemed persuasive. Reiriz et al. teach that the locus coeruleus (LC) contains about half of the total number of noradrenaline-synthesizing neurons. The LC gives rise to fiber systems that project throughout the CNS and undergo differentiation at about 12 days of gestational age in the rat. The central nervous system pertains to the brain, cranial nerves and spinal cord. It does not include peripheral nerves. Furthermore, LC neurons are a "type" of neuron of the CNS. Reiriz et al. teach an effect in LC neurons, this is not applicable to all CNS neurons. In addition, the instant claims still recite neural cells and read on in vivo methods. The scientific reasoning and evidence as a whole indicated that the rejection should be maintained.

  
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